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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

WARNING LETTER
NWE -20- 00W

February 3, 2000

VIA FEDERAL EXPRESS

Alan Small
President
ENDO Surgical Concepts, Inc.
86 Buckfield Lane
Greenwich, CT 06830

Dear Mr. Small:

During an inspection of your establishment located at 86 Buckfield Lane, Greenwich, CT on October 13, 1999 and January 6, 2000, our investigator determined that your establishment is the specification developer of sterile bone screws. You provide specifications to contract manufacturers who then return the finished devices to you for distribution. As such, you are a manufacturer, subject to the Good Manufacturing Practice requirements for medical devices since the bone screws are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures to ensure that each production lot of finished devices meets acceptance criteria. For example, you stated that you do not review batch records of the manufacture, packaging or sterilization processes before releasing finished devices for distribution.

During the inspection it was also noted that there was no documentation that lot 5C32M of interference screws had been sterilized. At the close of the inspection, you indicated that you would determine if the contract sterilizer had any records that would demonstrate this lot had, indeed, been sterilized. We have not heard anything from you since January 7, 2000. In your response to this Warning Letter, please inform us of the final disposition of this lot.

2. Failure to establish and maintain procedures for the identification of product during all stages of production and distribution to prevent mix-ups. For example, the batch records revealed that the lot numbers assigned by the finished product packager, Micro Med, cannot be traced back to the manufacturer's lot number of devices.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems of your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Karen N. Archdeacon, Compliance Officer, Food and Drug Administration, One Montvale Avenue, Stoneham, MA 02180.

Sincerely yours,

Michael R. Kravchuk
Acting District Director
New England District